Iontophoresis - Dexamethasone used here to help electrode attach to skin to put current through for tendonitis

preservatives - Anti-Microbial agents
- Kills cells, tissue or creatures
- Don't want to inject in spine with all the nerve endings
- Primarily injected in Elbows, Knees (no nerve endings)

lyophilize (lyophilization)
- process of taking out water out of substance and end up w/ sterile powder

Normal Saline - 0.9% sodium chloride
same salt content as our bodily fluids

Sulfan Blue - Dr's buying from us are using for Lymphatic staining.
"closer product chemically"

IU - International Units

Units - Natural Source Product
units of activity of drug (ie polymixin units/milligram)
"Potency of Drug" - potency from natural sources vary.

Aseptic - procedures performed under sterile conditions

Blue zone - outside sterile zone

DOJ_NECC001558338

- in patient pharmacy
- NECC Pharmacy
- Specialty Pharmacy
  - ~~op~~ w/ focus on
    - optomology
    - irrigation solutions
    - pain mgmt
  - start w/ products they can't get

Lymphazurin - can't get
- back-order until March
* Dye used in diagnostic centers to try + identify lymph nodes - sentinel lymph nodes - biopsy of lymph node
- Sulphan blue - is the same structure as lymphazurin
* using as visible an alternative

X - what I have heard other Dr's say

caine - anesthetic
- used to numb

- Math
- No confirmation call
- won't know if full order until arrive date

use contracts

- Pharmedium (can't do business in Ohio) (How do they confirm orders)
  - Latest News
    - Nov 1st 2006 - improved service code designation for admixtures
    - Feb 20th 2006 - Improved bar coding

not impressed
latest news 1 yr ago

Production
- NJ
- Mississippi

- History - 15 yrs old
  - 1,500 Hospitals
  - "Buy it, hang it + spike it" (CP's only other company that offer these)

* if you don't order what is contracted - they will charge you
* They do have minimums

Patient Safety
- CII nomenclature indicates schedule of drug. ???

* Do like Testimonial part of website

(google it)

CAPS
- 1991
- 1000 Hospitals = 23 locations across country

- re-calls
- 5 deaths - NJ, Maryland N.Y + Virginia
- FDA investigating

"Outsourcing allows the pharmacy to expand their services without added capital costs + additional staff"

Niche
TPN - Total patient nutrition
24 hrs - close by to make
- Cardiopyxic: not

?? "antibiotics in all ~~kkkkk~~ types of reservoirs"

?? class 10,000 clean rooms - (Better than ours??)

?? JCAHO accreditation
- Testing in house??

DOJ_NECC001558340

(NECC - 97
Ameridose - 06) - class 10
- class 5

DEA can regulate Both

- NECC - can do diff. concentrations
  - we can prepare from raw powder
  - from non sterile powders to sterile solutions

Ameridose - doesn't do powder - up
start from sterile solutions
"Admixing" 2 comm products mixed together
"Hybrid of Manufacturer + Pharmacy"

- MASS Board of Pharmacy -

- FDA - doesn't regulate us

- we're about choice for patient, pharmacist + physician

- ~~A~~
IV room manager - Ameridose

- .22 micron filter - filter impurities

- Solutions - suspensions ??

- All USP grade materials - FDA approved

DOJ_NECC001558341

4 things that make us different

Service: confirmation calls
- follow up
- 7-7 M-F we're available
- ~~Ask~~ Available 7 d

Turn-around: 48 hrs
- Daily, weekly, monthly, quarterly
- standing orders

Usable Dating - we can turnaround quickly
"Fresher products"
- competitor - >days
"we make to order"
- no credit back from compet.'l

Wide range of products + Sz
"6-10 products not available elsewhere
- cardiac
- OB
- c2's
- oral ad mixing . . .
- Sufentanyl

"can't do insulin. won't stay stable in any solution

DOJ_NECC001558342

Stability - potency range + - 10%

"sell product convenient to their need"
- Delivery when needed

Product Guaranty "14 day return policy"
- might be damaged in shipping

* Lifetime value of the customer
- not quible about crediting customer
- we'll overnight for free, if running late

Book club:
- The Goal
- It's not luck
- Necessary but not sufficient

- Sofia Psadis - ~~Head of~~
- Regulatory Compliance Officer
- part of Mass Board of Pharmacy * President Elect
- 20 yrs experience w/ Hospitals
- Any questions about sterility, stability

- Melanie - VP Quality Assurance
- environmental, training, [illegible]

DOJ_NECC001558343

Suspensions - cloudy
solutions - clear

* IV room manager - Ethanol
(have hard time getting)

- NDC # National Drug Code
  - unique identifier
  - for Recalls

Expedite — Lani - X 605 - Ameridose
Madeline x 616 - NECC - (consult on complaints)
or Tiffany - where, when, how much
very specific

(P) (PF) - preservative
" free

Diluent - fluid that drug comes in

Pricing - "Go back to my Operations Team"
"I'm on your side"
"I want to earn your business"
- Please fax me an invoice and I'll beat them down for you.
- more volume the better

DOJ_NECC001558344

(11 yrs - never a recall)

- personal Development plan

\ committed to long haul. can't afford mistake

- "we meet or exceed all USP 797 guidelines"

Phone-calls w/ Stan

NECC Pharmacy - Introduce you to NECC - we are a specialty pharmacy. Are you using .....

- ~~drug~~ in-patient pharmacy
  - ~~Buyer~~ pharmacy Buyer available?

Alan - room temp irrigations

what to look for w/ compounding

1) National or Local — Amneal - Tampa FL
2) Regional - Harlkey - California market
3) 100's local pharmacies — Medshop - Texas, Oklahoma, Arkansas

- competition

- Safeguards in our quality control
  - state of the art lab
    - far exceeds FDA regs

DOJ_NECC001558345

[redacted]

- Testing - we test every med we make
  - we make batch & quarantine the batch then send outside lab 4 testing
    - sterility
    - endotoxin - "biproduct of the sterility process

(H.W) .22 micron filter

2 ways sterilize
1) filter - what is size of of filters?
2) Heat - if too many endotoxins after heat "not good" should be range of acceptable # of endotoxin

- potency
  - Assay it " to determine what concentration it has

National, Test every Batch, Environment
"Certificate of Acceptance"
"Microbiology report"

Class 10 - no more than 10 particles per square foot

" we [illegible] exceed the [illegible] minimum requ[illegible]

DOJ_NECC001558346

- IV room manager

we are a nationally licensed specialty pharmacy

1 stop shop for IV room pharmacy needs

Ethanol
Irrigation systems

Have you heard of us?
- we work with over a thousand hospitals across country providing ...

products - Ethanol
irrigation solutions
LET
Alum
Dialation drops

Benefits - - save ~~$~~ Reduce labor costs
- save time
- Reduce your waste
- free up your staff to focus on other initiatives
- Provide more usable data

- what are you preparing in house now that is difficult to make or you would like to outsource

DOJ_NECC001558347

IV admixing

- Oxytocin
- Magnesium
- Calcium Gluconate

CII

- Sufental
- Morphine
- methadone — (only us)

OR Syringes

Diluents

3 Most common

- D5W - Dextrose 5% water
- Normal Saline 0.9 %
- ~~LR~~ LR Lactated Ringers
- D10 - Dextrose 10% water
- D5W/LR
- ~~STW~~ STW - sterile water

Concentration / strength

- ~~mcg~~ mL - milliliters
  ~~mg~~ Mg - milligrams
  ~~mcg~~ Mcg - micro
  ~~mEq~~ mEq - Mmols

DOJ_NECC001558348

Dose Size

- 150 ml and above have to be in bag (too big for syringe)

10 mL and lower syringe only

250 - 150 ml - bag or cassette

25 - 60 ml - syringe or cassettes

Delivery Device - Bag, syringe or cassette

NEC 250 - 500 ml bags (irrigation)

Ethanol - (ask Barry)

DOJ_NECC001558349

- intrathecal

2 manufacturers of IT Pumps
- medtronic - 85% of market
- Johanson + Johanson
- used for pain - implanted inside by hip

very patient specific

why used - M.S.
- chronic pain

"courtesy prescription"

Buffered - helps not sting when injected

DOJ_NECC001558350

Extranet Training!

Dashboard - view accounts by dollars . . . . .

print this out

Admin -
- Process ~~Redview~~ Builder
- OST
  - lead - no contact
  - prospect - spoke
  - needs analysis
    - hot buttons "what we can offer
  - Proposal
  - Agree to order (verbal)
  - check Pharmacy for order
  - client follow-up
  - upsell
  - Finished or lost deals

red - past due
yellow - future
green - today

DOJ_NECC001558351

pipeline

- Clients - already ordering from us
  - trying to use that to get other business

- Customers - order less frequently
  - looking to upsell in next 30 days

- Prospects - intro to pipeline
  but no contact

DOJ_NECC001558352

have to be sterile injected into people

high risk. means from non sterile

{ sterile. product that is devoid of any bacteria, no living micro organisms in it

2 ways sterilize

- Filter - micron filter/ solution - pulls out micro-organisms

"your legal dept. would like you to outsource the liability"

"we're problem solvers" "solve medication problems"

"chemical stability"

USP 797. sterile
USP 795. non sterile

"our capabilities"

"can't tell them how to use our products

DOJ_NECC001558353

"off label use"

- Dr's can prescribe for what they want, but we can't talk about

- behind commercial use there are; dosage forms, concentrations

NECC - Pharmacy - creating products
Amerisource - Manufacturer

Our products need to be used not re-sold

- Mom + Pops
"They're dabbling in it"

- Joint Commission accredits hospitals w/out - they can't bill Medicare & Medicaid

Sourcing out production & liability

DOJ_NECC001558354

- what is best
  - sulfan blue.
  -

were been making since 2002 { sulfan blue - closest

Lymphazurin was made from sulfan blue

not patentable. so they could make new chemical so they can patent it

" This is a closer product than methalane blue "

LET - very hard to make

- epinephrin - potent nasal constrictor
  - stops bleeding

Bacitracin - very unstable - have it out to 6 weeks

1 month at a time { irrigation solution: polymixin, neomycin (it's like neosporin)

3 main uses: 1) ortho - when open wound clean it out
- Rx/Use 2) plastic surgery
3) Surgery

come in - bags
- bottle

DOJ_NECC001558355

(like underarm deodorant)
- causes coagulation
↓
chelating (freelating)

Alum - bladder cancer - helps break down in tissue - if bleeding internally - they will pump in Alum to toughen up the tissue to stop bleeding

(pump in Alum to toughen-up the tissue + stop the bleeding)

Drug Budget
man hour budget
} 2 different thing

DOP should use vs because drug can be billed elsewhere - like the end user

"Feel, Felt, Found"

"We're an extension of your hospital's pharmacy"

DOJ_NECC001558356

Do we need to say LET gel?

Names - - Every drug has to be coded + in their database
- For billing ~~[illegible]~~ purposes

"In office use" - we don't have that

"we have unique formulations"

"blind items" must believe the quality we ~~provide~~

No-one else has
- customer service
- - other companies not sure when can deliver
"whole package" we offer
- shouldn't sell unique product on price only

99% of our sterile products are produced by pharmacists not techs

"we know what they're looking for so we've done it all

DOJ_NECC001558357

- process, people, facility, packaging"

"unique facility
" " product

"make them show us what this other place does" Testing.....

- more a better choice long term

"what would you like, How would you like if" "let me find out if we can"

- " sterility + endotoxin - we could do ourselves - so we can't fudge testing"

"sterility" - devoid of any live microorganisms - anything that can grow

perfect growth for like "stagnant pond"
- fungi
- mold
- viruses
- bacteria

"looks like snow globe" - Suspension - water based - (has to be even when shook)
- ingredient is not soluble in water
- when shake up you re-suspend

problem with suspension

have to heat { you can't filter
you'll filter out active ingredients

- autoclave - pressure cooker
  - raises temp + pressure
  - boils it but at higher temp than water
  - pressure will increase temp.

~~Endotoxi~~

shows you you had bacteria, viruses but were killed away

lets you know you have a dirty process somewhere"

— Endotoxins - "Pyrogens"
- breakdown products of sterility"
- can't filter them "too small"
- endotoxins when injected will give flu like symptoms then immune system will respond
"won't kill you" they don't replicate

- ~~Validation~~ There is a lot of ways to make a product. we do it right "how is your competitor making it?"

DOJ_NECC001558359

- FDA registered labs
  - what we use to test

- we're not microbiologist - everyone should source it out

"we care more than hospital pharmacy" that's all we do

~~Hippa~~ - into driver leaves our facility"

"How much
"what's ideal volume
"

"this is opportunity to get exactly what you want"

(<2's - definite script for each patient)

*individuals only - black + white only - no grey area

Non-sterile services -

~~*~~ (Quality + Credibility) what we sell

~~*~~ know when to kick to Barry

Pain Mngmt -

- Physiatrist } rehab drs
- Anesthe. } dealing w/ recovery
  eg - spinal injury
  a lot of pain involved w/ these injuries.

central to pain in body { Brain, central nervous system, spine

Pain physician - prescribe oral meds
- inject meds in central nervous center

"triamcinolone" and all our steroids are "preservative free"

- Steroids - inject into spinal cord to reduce ~~inflamma~~ inflamation to
  - intrathecal space - space right outside main spinal cord - outside that

DOJ_NECC001558361

preservatives - doesn't help w/ shelf life
- it makes it a multi-dose vial
= "antimicrobial agents"

what do - prevents anything from replicating

- if going into epidural space it should be preservative free

most popular preservatives { "Benzel alcohol"
"Benzal Kono

only single dose vial when P.F.

* anything injected in or around spine is preservative free"

- Phenol - inject to deaden nerve
- very potent anesthastetic

neuro-lices - deaden nerve permanently

why major drug companies not doing it { - Market not large enough
- Stability
- Drug companies can't make every dose form

radiopaque - any substance that does not let x-ray penetrate (comes out white on x-rays)

DOJ_NECC001558362

(Baclofen)

Pain Centers (cont.) or Rehab Centers

- intrathecal pumps
  - "titanium hockey pucks"
  - these are people at the end of the line "tried everything else"
  - "chronic pain situation"
  - usually in abdomen
  - run catheter from pump into intrathecal space right outside the spinal cord

* bypass liver go right into spinal cord

morphine / baclofen
- only 2 drugs that are FDA approved that are used in the IT pumps
- they have to change all the time because patient will develop a tolerance

"Don't get systemic side effects w/ pumps because at site of action"

IT pumps made by Medtronics
- "shipped in tamper evident bags"

* Don't test phenol nothing can grow in it

Repository Acetate + phosphate

DOJ_NECC001558363

Controls

- IT pumps

- Cocain hcl 10% eye drop
1ml in 3ml dropper.
- used for diagnostic agent for an ophthalmic condition known as "Homers Syndrome"

Suspensions (particulates)
- longer acting
Solutions - fast acting

SDV - single Dose vial
- doesn't come larger than 5ml - (Don't need more than 5 for single dose ever)

DOJ_NECC001558364

sclerosing agent -- hardens

- preservatives - "potent stuff"
  - anti-microbial agents - "kill cells"

"Killing living tissue or creatures"

- neurotoxic agents
  - don't want to inject in the spine with all those nerve endings
  - designed to be injected in elbow, knees.. * not spine
    - no nerve tissue there

dangerous to use preservative on eye - optic nerve + retina very sensitive

USP 797

environment - type of clean room
- cleaning schedule
- cleaning agents
  - how much for cleaning process
- Antimicrobial cleaning agents

DOJ_NECC001558365

P+T pharmacy + therapeutics committee
meet monthly usually

- powder - (lyophilize) lyophilization process of taking out water + add. w/ sterile powder
  - in liquid state - must be unstable
    "starts to break down"

with commercial products
- already have certain concentrations
- can't alter as much as need like.

what we need { Drug concentration volume
1) what container - what do you really want?
2) How much use

- no labeled use for any of our product } we have to follow labeling laws
- Dr's can do what they want "unlabeled use"

normal Saline { 0.9 - sodium chloride
- same salt content as our bodily fluids (blood)

(for lymphatic staining)
Sulfan Blue
methylene Blue - chemically it's a closer product
- been around forever (oncology dept)
- had to come out w/ patent
- took molecule + spun it and added new (perfect blue dye)

*call customers we sell this to + are using it for this

doing for six years

DOJ_NECC001558366

Cardio green - pump into cardiac arteries
to see blood flow

normal Saline - 0.9 = 9 milligrams per milliter
= 9mg/ml

IV - international units (potency)
units - natural source product
units of activity of drug
ie polymixin - units/milligram
"units of activity or potency)

potency from natural carries vary "not same"

KV = 1000 units
MV = milliunits

LAT
- adrenaline
- epinephrine 4

Names * ship out to you in good faith the first month supply
"This is the closest way we have.
At the end of the month you'll know if he used it or not.

DOJ_NECC001558367

Coronary Artery Bypass } "cabbage"

GALA

500-250 cc Bottles (must be shipped cold)

- 4 active ingredients in solution
- open heart surgery "cabbage procedure"
- Bypass surgery
- ~~surfa~~ saphenous vein from leg
- grafted to heart itself

Biggest problem - Once harvested from leg - tissue starts to die immediately.

* Has to be compounded
- only source to a couple of ingredients only come in powder

IV

IV Room Manager -

"This is what we're producing for other hospitals"

Pain

* orthopedic -
- Terminally ill cancer patients with 3-6 months left
- Also, chronically in-pain patients "End of the line"

IT pump
5-yr battery

- eliminate side effects (i.e. "drowsiness")
- Morphine, Baclofen. only 2 commercially avial. refills. only 2 concentrations

DOJ_NECC001558368

* specially designed needle which can puncture pump — Buy kit from medronix

* we sell just syringe

* we have 1,500 - 2000 combinations for our refills

Pumps hold 40ml - about 30 day supply
May only be 10 day

- Don't want 1 drug at high concentration
- Need multiple drugs at diff. concentration because they have different active agents, effect receptor sites differently.

Anazeo - Major competitor
- we will compete on price

Brand name "Lioresal" — Baclofen: muscle relaxer (Medronix - dos comes in only these)
- 2000 mg/ml
- 500 mg/ml

* physiatrists use Baclofen

* we produce 5000 mg/ml
- Cerebal palsy
- Multiple sclerosis

will have IT pumps for just Baclofen

helps with spasms

- pediatrics dealing w/ CP + MS

PhysMed
Rehab Center
or
Pain Center

DOJ_NECC001558369

"Buying piece of mind"

- 1st ever compounding only pharmacy

- what are products that only we offer

- methacholine Kit
  - instant test to see response - find out whether asmathic

- our own stability testing
  - we've invested a lot of money

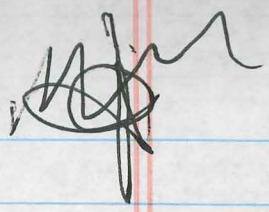
"High risk sterile products Under Contract?
  - we've never seen it.

ESI - (Epidural steroid Injection)
- would your doctors be interested in a non-particulate P.F. steroid injection?

"we have liability insurance"

Name Drops
- University of Michigan, Wisconsin, Maryland
- Emery Healthcare
- Mass General
- Brigham + Womans

DOJ_NECC001558370



Betamethasone + Kenalog

· midwest allergies